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Ostfalen, E-39179, Barleben, Magdeburg, Germany. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 34 of the Counterclaim.

35. EKF-Diagnostic Sales, GmbH, admits it is a German corporation, with its principal place of business at Edendorfe Chaussee 3, Technologie Park Ostfalen, E-39179, Barleben, Magdeburg, Germany. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 35 of the Counterclaim.

36. EKF-Diagnostic Sales, GmbH, admits that EKF-Diagnostic Manufacturing, GmbH, is a German corporation, with its principal place of business at Edendorfe Chaussee 3, Technologie Park Ostfalen, E-39179, Barleben, Magdeburg, Germany. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 36 of the Counterclaim.

37. EKF-Diagnostic Sales, GmbH, admits that it is a counter-defendant and denies that EKF-Diagnostic Manufacturing, GmbH, is a counter-defendant. Further, EKF-Diagnostic Sales, GmbH, admits that it and EKF-Diagnostic Manufacturing, GmbH, are wholly owned subsidiaries of EKF-Diagnostic, GmbH. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 37 of the Counterclaim.

38. EKF-Diagnostic Sales, GmbH, admits that its action is for declaratory judgment that U.S. Patent Number 5,764,457 is invalid and unenforceable and not infringed by EKF-Diagnostic Sales, GmbH, either directly or as an inducing or contributory infringer. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 38 of the Counterclaim.

39. Denied.

40. EKF-Diagnostic Sales, GmbH, admits that it sells the cuvettes which are the subject matter of this lawsuit to Stanbio Laboratory L.P. ("Stanbio"). The remainder of the allegations in paragraph 40 of the Counterclaim are conclusory in nature and EKF-Diagnostic

Sales, GmbH, is without knowledge or information sufficient to enable it to admit or deny those allegations and therefore EKF-Diagnostic Sales, GmbH, denies the same.

41. EKF-Diagnostic Sales, GmbH, admits that venue is proper in this District. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 41 of the Counterclaim.

42. Admitted.

43. EKF-Diagnostic Sales, GmbH, admits that the '457 Patent purports to "cover" the devices recited in its Claims 1-7.

44. EKF-Diagnostic Sales, GmbH, lacks knowledge or information sufficient to enable it to admit or deny the allegations set forth in paragraph 44 of the Counterclaim, and therefore denies the same.

45. EKF-Diagnostic Sales, GmbH, lacks knowledge or information sufficient to enable it to admit or deny the allegations set forth in paragraph 45 of the Counterclaim, and therefore denies the same.

46. Stanbio has in the past offered for sale and sold the HemoPoint® H2 Hemoglobin Measurement System for measuring hemoglobin levels in blood samples. Except as so admitted, EKF-Diagnostic Sales, GmbH, lacks knowledge or information sufficient to enable it to admit or deny the remainder of the allegations set forth in paragraph 46 of the Counterclaim, and therefore denies the same.

47. HemoPoint ® H2 Microcuvettes can be used with the HemoPoint ® H2 Hemoglobin Measurement System. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 47 of the Counterclaim.

48. Per an agreement between EKF-Diagnostic Sales, GmbH and Stanbio, EKF-Diagnostic Sales, GmbH, sells and delivers cuvettes to Stanbio for sale in the United States. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 48 of the Counterclaim.

49. Stanbio has offered for sale HemoPoint ® H2 Microcuvettes under the part numbers 3010-100 (2 containers @ 50 cuvettes each) and 3010-200 (4 containers @ 50 cuvettes each). Except as so admitted, EKF-Diagnostic Sales, GmbH, lacks knowledge or information sufficient to enable it to admit or deny the allegations set forth in paragraph 49 of the Counterclaim, and therefore denies the same.

50. EKF-Diagnostic Sales, GmbH, admits that it sells and delivers cuvettes to Stanbio for sale in the United States. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 50 of the Counterclaim.

51. In response to paragraph 51 of the counterclaim, EKF-Diagnostic Sales, GmbH, repeats and realleges the admissions and denials previously set forth in this Reply.

52. EKF-Diagnostic Sales, GmbH, admits that it sells and delivers cuvettes to Stanbio for sale in the United States. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 52 of the Counterclaim.

53. EKF-Diagnostic Sales, GmbH, admits that it had knowledge of the '457 patent prior to selling and delivering cuvettes to Stanbio for sale in the United States. Except as so admitted, EKF-Diagnostic Sales, GmbH, denies each and every allegation contained in paragraph 53 of the Counterclaim.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

PRAYER

Plaintiff denies that Defendants are entitled to any relief whatsoever.

AFFIRMATIVE DEFENSES TO THE COUNTERCLAIM**FIRST AFFIRMATIVE DEFENSE****(Non-Infringement)**

None of EKF-Diagnostic Sales, GmbH's, activities or products have infringed any valid and enforceable claim of the '457 Patent. EKF-Diagnostic Sales, GmbH, has not contributed to the infringement of any valid or enforceable claim of the '457 Patent. Nor has EKF-Diagnostic Sales, GmbH, induced others to make, sell, offer for sale or import any products infringing any valid or enforceable claim of the '457 Patent.

SECOND AFFIRMATIVE DEFENSE**(Patent Invalid/Unenforceable)**

Upon information and belief, the '457 Patent is invalid and/or unenforceable for failure to comply with the requirements, conditions, and provisions set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE**(Unenforceable Due to Misconduct)**

Upon information and belief, the '457 Patent is unenforceable due to HemoCue's misconduct before the U.S. Patent and Trademark Office, including its failure to disclose material and known prior art as required by, among other requirements, 37 C.F.R. § 1.56. By way of example only, HemoCue did not disclose to the U.S. Patent and Trademark Office relevant facts concerning HemoCue's own commercially sold cuvettes although this information was material under 37 C.F.R. § 1.56. See, e.g., *Bruno Indep. Living Aids v. Acorn Mobility Servs.*, 2005 U.S. App. LEXIS 387 (Fed. Cir. Jan. 11, 2005). Moreover, during prosecution of the '457 Patent, HemoCue did not disclose to the U.S. Patent and Trademark Office ("USPTO"),

U.S. Patent No. Des. 337,388, which issued to some of the same inventors listed on the '457 Patent. See, *Id.* Further, HemoCue did not disclose to the USPTO during prosecution of the '457 Patent: "HemoCue B-Hemoglobin Reference Manual," dated January 1990; German Instructions for Use of the "HemoCue-B-Hemoglobin Photometer," dated December 1991; and, U.S. Trademark Registration Number 75676649 which identifies a use since 1982 of cuvettes having patented features.

FOURTH AFFIRMATIVE DEFENSE

(Laches/Estoppel/Waiver/Acquiescence)

HemoCue' counterclaim for patent infringement is limited or barred by the equitable doctrines of laches, estoppel, waiver, and acquiescence. Upon information and belief, HemoCue, in its several pleadings filed in the now consolidated suit with Stanbio (i.e., SA 03 CA 1080 OG), affirmatively avoided objecting to Stanbio's sales of the subject matter cuvettes or stating that the subject matter cuvettes infringed the '457 Patent, and consistently denied that it objected to the cuvettes until July 9, 2004. Further, Stanbio provided HemoCue with samples of the subject matter cuvettes in 2003 and requested HemoCue in writing advise Stanbio in HemoCue believed the cuvettes infringed the '457 Patent. HemoCue failed to respond to Stanbio's direct request. Further, in response to Stanbio's pleading and affidavits stating that Stanbio had a reasonable apprehension that HemoCue intended to file suit against Stanbio in San Diego alleging that Stanbio infringed the '457 Patent, HemoCue's pleading and affidavits filed with this Court continually denied that HemoCue intended to file suit that the subject matter cuvettes infringed the '457 Patent .. right up until HemoCue filed suit on July 9, 2004, in San Diego federal court alleging infringement of the '457 Patent.

FIFTH AFFIRMATIVE DEFENSE**(Unclean Hands/Patent Misuse/Antitrust Violations)**

On information and belief, all or part of HemoCue's Counterclaim is barred by HemoCue's unclean hands, patent misuse, and violation of the antitrust laws of the United States. In particular, HemoCue failed to disclose material information concerning relevant prior art to the Patent and Trademark Office. Additionally, even though HemoCue had information that cast substantial doubt upon the validity of the '457 Patent and the alleged infringement by EKF-Diagnostic Sales, GmbH, HemoCue still filed the Counterclaim in this lawsuit attempting to enforce the '457 Patent.

SIXTH AFFIRMATIVE DEFENSE**(Failure to Mitigate)**

On information and belief, HemoCue has failed to act reasonably to mitigate the damages alleged in the Counterclaim.

SEVENTH AFFIRMATIVE DEFENSE**(Reservation of Rights)**

EKF-Diagnostic Sales, GmbH, reserves the right to amend and supplement its responses and affirmative defense after further discovery.

PRAYER

WHEREFORE, EKF-Diagnostic Sales, GmbH, respectfully requests this Court deny all relief sought by Counterclaimants with prejudice and request all other relief, both at law and in equity, to which Plaintiff may show itself to be justly entitled.

Dated: February 3, 2005

Respectfully submitted,

Jody Factor

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CERTIFICATE OF MAILING


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